June 17, 2003

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RE: draft *Chronic Toxicity Summary,* Silica (Crystalline, Respirable)

Dear Dr. Salmon,

I am writing this letter on behalf of the International Diatomite Producers Association ("IDPA"), a trade association of producers of diatomaceous earth products that was formed in 1987. IDPA includes in its membership companies both doing business and operating facilities in the state of California. IDPA sponsored one of the principal epidemiology studies relating to crystalline silica exposure and the potential risk of lung disease, and has been a leader in developing safe work practices for the use and handling of diatomaceous earth, which contains crystalline silica.

OEHHA recently released its draft *Chronic Toxicity Summary* for respirable crystalline silica. There has been an ongoing debate regarding this issue for more than a decade. As OEHHA recognizes, crystalline silica is widely present in California. Indeed, its most prevalent polymorph, alpha-quartz, constitutes 12% of the earth's crust.

Prolonged and excessive exposure to respirable crystalline silica dust is a known cause of silicosis. Exposure to crystalline silica dust has also been associated with an increased risk of lung cancer. The scientific community is widely split on the latter issue, but most scientists believe that, if there is a relationship, it is a weak one, and more likely than not carcinogenicity is a threshold phenomenon with silicosis (fibrosis) as a precursor. The disease outcome of exposure to crystalline silica has historically been a workplace issue regulated by California and federal OSHA; we see no substantive information to suggest that it is an environmental issue.

The *Chronic Toxicity Summary* for respirable crystalline silica and the associated REL (Reference Exposure Level) have very substantial implications both within and outside of California. The scientific literature on health effects of crystalline silica is very extensive, and interpretation of the studies (including those on which OEHHA principally relies in deriving the REL) is far more complicated and controversial than the draft *Toxicity Summary* suggests.

OEHHA has proposed an REL of 3 $\mu g/m^3$. The recommended chronic REL, which is below even the default level suggested by the USEPA (5$\mu g/m^3$), does not accurately reflect the most recent scientific information available on the subject. For example, Lopipero and Smith in a *Quantitative Risk Assessment for Crystalline Silica Using Human Epidemiological Data*, 1999, concluded that silicosis is not expected to occur at this exposure concentration (5 $\mu g/m^3$). Furthermore, OEHHA

cites no credible evidence of silicosis occurring in the general population at exposure levels below those found in a workplace environment.

OEHHA notes that "silicosis is still being diagnosed in workers exposed at currently allowable occupational levels." We are aware of no evidence to support this statement. While US OSHA's recent SEP (Special Emphasis Program) on crystalline silica reported significant exposures at levels exceeding the current PEL, there was no evidence presented that the diagnosis of new cases of silicosis was or is being reported in facilities in compliance with the current PEL. The SEP results simply show that overexposures continue to occur in inadequately controlled workplaces.

In its draft document, OEHHA cites a few examples of reported environmental silicosis; however, at the same time the agency acknowledges that the exposure levels "were very high and thus similar to some occupational exposures." Workplace exposure limits for respirable crystalline silica range from 50 to 100 $\mu g/m^3$. When converted from the workplace to environmental values by time adjustments for hours per day, days per week, and a continuous 70 year lifetime of exposure, the limits are reduced to 7 to 13 $\mu g/m^3$, substantially above the REL proposed by OEHHA. Furthermore while OEHHA has acknowledged a justification for reducing the interspecies uncertainty factor (UF_H) from the default value of 10 to 3, no scientific data is presented to support any factor to protect children, the elderly and females. Such uncertainty factors are more appropriate when animal data is the basis for the establishment of a risk factor and human evidence is lacking. OEHHA even acknowledges that "the workers who developed silicosis at low silica concentrations are by definition the most sensitive workers to silica-induced silicosis."

In its derivation of an REL, OEHHA has relied primarily on Hnizdo and Sluis-Cremer's 1993 study of South African gold miners. It has recently been reported that the exposures to quartz reported in this study were underestimated by a factor of approximately 2 (Gibbs and Du Toit 2002). This alone would have significantly increased OEHHA's derived value. In addition, OEHHA calculated from this study that there was a 1.9% incidence of silicosis (9 cases/474exposed) at exposures to 0.9 mg/m^3-yr silica. The denominator should have also included all of the workers who passed through that level and who received additional exposures, but did not get silicosis, as discussed by G. Berry[1] in his response to the REL to be submitted by the Crystalline Silica Panel. The authors of the study (Hnizdo and Sluis-Cremer) found a 0.4% incidence at 1 mg/m^3-yr.

As a supportive study, OEHHA cites Hughes, et al.'s 1998 study of diatomaceous earth workers. The draft implies that quantitative measurements were used to develop exposure data. The quantitative measurements used were, in fact, for total dust, not crystalline silica, and extrapolations were made for years prior to 1948. Further, the development of the crystalline silica (cristobalite) content of the dust was based on estimates rather than measurements. Thus, the assigned exposure assessments made for individual job classifications were at best semi-quantitative. For the years prior to 1948, where the greatest excesses of disease are shown, the silica estimates were based on multipliers from estimated ordinals and thus could not even be considered semi-quantitative. Furthermore, silicosis cases in this study were defined in terms of chest X-ray readings as small opacities of profusion of 1/0 or greater, considering both rounded and irregular opacities. This again results in an overestimation of the cases by comparison to the Hnizdo, Sluis-Cremer study and others who generally use 1/1 as the basis for cut-off.

We are further concerned that at any given time, background ambient levels can be essentially equal

[1] Some comments on the Chronic Toxicity Summary Silica (Crystalline, Respirable), May 19, 2003

to or greater than the proposed REL of 3 μg/m^3. As an example, a recent study conducted in Santa Barbara County for the LIWG (Lompoc Interagency Working Group) reported background ambient levels ranging from a low of 0.2 μg/m^3 in Buellton to a high of 2.6 μg/m^3 in Santa Maria, and nationally a range of from 3-8 μg/m^3 has been reported by the USEPA, hardly insignificant in relation to a proposed REL of 3 μg/m^3. OEHHA's treatment of this important issue is minimal at best. OEHHA should examine the subject more thoroughly to provide the appropriate guidance to the California Air Resources Board (CARB) and subsequently to the local Air Districts on how ambient levels might be dealt with in terms of regulatory compliance to provide some uniformity in how it is handled state-wide at the air district level.

The measurement of low levels of respirable crystalline dust has significant limitations and here again OEHHA should provide some guidance to CARB and the local Air Districts in their enforcement policies. For example:

> The PM_{10} particle size method used in EPA Method 501 can have errors up to 15% (page 93).
>
> USEPA's ambient air test method for PM (40 CFR 50 Appendix J, Section 4) indicates precision is 5ug/m^3 for ambient concentrations of 80 and below.
>
> Federal Register, Tuesday April 15, 2003, pg 18467 discusses modeling errors of +/- 10 to 40%.
>
> The AIHA PAT (Proficiency Analytical testing) program reports a standard deviation for crystalline silica analyses of ± approximately 20%.

Lastly, there are significant differences in the collection characteristics of the equipment used to measure ambient levels, determine stack emissions levels, and the personal exposure monitoring levels on which the REL was based.

The above issues should be addressed to provide guidance to CARB as they raise questions regarding the ability to reasonably and accurately compare and measure respirable crystalline dust at the recommended REL of 3 ug/m^3.

Sincerely,

MJMirliss

Mel J. Mirliss
Executive Director, IDPA